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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/348,815	07/08/99	LI	H PF126P1D1

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HM22/0118

EXAMINER

ZARA, J

ART UNIT	PAPER NUMBER
1635	11

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

File

**Office Action Summary**

Application No. 09/348,815	Applicant(s) LI et al
Examiner Zara, Jane	Group Art Unit 1635

Responsive to communication(s) filed on Oct 17, 2000

This action is **FINAL**.

Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle* 1035 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

**Disposition of Claim**

Claim(s) 1 and 21-96 is/are pending in the application.

Of the above, claim(s) 1 is/are withdrawn from consideration.

Claim(s) \_\_\_\_\_ is/are allowed.

Claim(s) 21-96 is/are rejected.

Claim(s) \_\_\_\_\_ is/are objected to.

Claims \_\_\_\_\_ are subject to restriction or election requirement.

**Application Papers**

See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.

The specification is objected to by the Examiner.

The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

All  Some\*  None of the CERTIFIED copies of the priority documents have been

received.

received in Application No. (Series Code/Serial Number) \_\_\_\_\_.

received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

Notice of References Cited, PTO-892

Information Disclosure Statement(s), PTO-1449, Paper No(s). 1

Interview Summary, PTO-413

Notice of Draftsperson's Patent Drawing Review, PTO-948

Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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## **DETAILED ACTION**

### ***Election/Restriction***

Applicant's election with traverse of Group II, claims 11, 12 and 19 in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the claims of Group I should be rejoined and examined with those of Group II. This is not found persuasive because Group I, drawn to polynucleotides, is a chemically, structurally and functionally distinct product than the product of Group II, which is drawn to proteins, and these two distinct groups would therefore require separate searches and considerations which would not be coextensive.

The requirement is still deemed proper and is therefore made FINAL.

Claim 1 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

Claims 21-97 have been examined in the instant Office action as indicated below.

### ***Claim Objections***

The numbering of claims is not accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

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No claim 23 was included in the amendment filed October 17, 2000, Paper No. 7.

**Claims 24-97 are renumbered as claims 23-96.**

Claims 1 and 21-96 are pending in the instant application. Claims 21-96 have been examined in the instant Office action as indicated below.

***Claim Rejections - 35 USC § 112***

Claim 49 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term “claim 50 contiguous comprising” needs to be corrected for clarification.

Claims 23, 25, 27, 29, 31, 33, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 61, 65, 67, 69, 71, 74, 76, 78, 80, 82, 84, 86, 88, 90, 92, 94 and 96 are rejected under 35 U.S.C. 112, second paragraph, as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. “Heterologous” does not further limit these dependent claims.

***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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Claims 21-96 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

The specification as filed does not disclose or provide any evidence for the function of the claimed amino acid sequences of SEQ ID NO: 2 or its fragments, nor for the function of amino acid sequences which share some homology with SEQ ID NO: 2, such that another non-asserted specific and substantial credible utility would be well established. Additionally, there is no art of record that discloses or provides any evidence that discloses a function of the amino acid sequences of SEQ ID NO: 2 or its fragments, nor for the function of amino acid sequences which share some homology with SEQ ID NO: 2, such that another non-asserted specific and substantial credible utility would be well established. With regard to the asserted use of the claimed amino acids, the function of the polypeptide, its fragments, or homologs, their function is not specifically known and the mere assertion that they stimulate cellular proliferation because they share sequence homology with other growth factors would not be accepted by one skilled in the art as being reasonable or credible in view of the contemporary knowledge in the art. It is known for nucleic acids as well as proteins, for example, that even a single nucleotide or amino acid change or mutation can destroy the function of the biomolecule in many instances, albeit not in all cases. The effects of these changes are largely unpredictable as to which ones have a significant effect versus not. Therefore, the citation of sequence similarity results in an unpredictable and therefore unreliable correspondence between the claimed biomolecule and the indicated similar biomolecule of known function and therefore lacks support regarding utility

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and/or enablement. Several publications document this unpredictability of the relationship between sequence and function, albeit that certain specific sequences may be found to be conserved over biomolecules of related function upon a significant amount of further research. See the following publications that support this unpredictability as well as noting certain conserved sequences in limited specific cases: Gerhold et al.[BioEssays, Volume 18, Number 12, pages 973-981{1996}]; Wells et al.[Journal of Leukocyte Biology, Volume 61, Number 5, pages 545-550 (1997)]; and Russell et al.[Journal of Molecular Biology, Volume 244, pages 332-350 (1994)]. Homology does not imply function. Since there is no evidence on the record for the function of the disclosed amino acid sequences of SEQ ID NO: 2, its fragments or its homologs, the asserted utility is inoperative and is therefore not credible.

Claims 21-96 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. The specification discloses amino acid sequence of SEQ ID NO: 2. The specification also discloses the expression of the polypeptide encoded by SEQ ID NO: 2 in various expression systems, including Cos cells. No function of said translated product has been disclosed in the instant specification, nor in any parent applications. In addition, no function of fragments or homologs of said translated polypeptide has been disclosed in the instant specification, nor in any parent applications. One skilled in the art would not accept on

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its face the expression of the translation product of SEQ ID NO: 2 in a transfected host cell as being representative or correlative of any molecular or cellular function of that product.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-96 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This rejection is based on the revised guidelines for written description, effective December, 1999. The specification and claims do not indicate what distinguishing attributes are concisely shared by the members of the genus comprising polypeptide fragments of SEQ ID NO: 2, nor of amino acid sequences which are heterologous to SEQ ID NO: 2, nor fragments derived therefrom. The specification does not place any limit on the number of amino acid substitutions, deletions, insertions and/or additions that may be made to SEQ ID NO: 2 or its fragments. Thus the scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Concise structural features that could distinguish compounds in the genus from others in the superfamily are missing from the disclosure. No common structural attributes identify the

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members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics concisely identifying members of the proposed genus, and because the genus is highly variant, the description provided for defining members of the family of molecules which comprise SEQ ID NO: 2, as well as homologs and fragments thereof, is insufficient. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus claimed. Thus, applicant was not in possession of the claimed genus.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See Vas-Cath at page 1116.)

Additionally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.* , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli* , 872 F.2d 1008,

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1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claims 21, 23, 25, 27, 30-34, 36, 38, 40, 42, 44, 46, 51-59, 61, 63, 65, 68-72, 74, 76, 78, 80, 82, 84 and 89-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Purchio et al.

Purchio et al teach isolated polypeptides comprising a minimum of 30 to 50 contiguous amino acids of SEQ ID NO: 2. Purchio et al teach isolated polypeptides comprising amino acid sequences heterologous to SEQ ID NO: 2 (See alignment attached to the enclosed reference; also see Purchio et al: figure 1, SEQ ID NO: 2, claim 2).

Claims 21, 23, 25, 27, 30-34, 36, 38, 40, 42, 44, 46, 51-59, 61, 63, 65, 68-72, 74, 76, 78, 80, 82, 84 and 89-96 are rejected under 35 U.S.C. 102(b) as being anticipated by Latinkic et al.

Latinkic et al teach isolated polypeptides comprising a minimum of 30 to 50 contiguous amino acids of SEQ ID NO: 2. Latinkic et al teach isolated polypeptides comprising amino acid sequences heterologous to SEQ ID NO: 2 (See alignment attached to the enclosed reference; also see Latinkic et al: Figure 1).

Claims 21, 23, 25, 27, 30-34, 36, 38, 40, 42, 44, 46, 51-59, 61, 63, 65, 68-72, 74, 76, 78, 80, 82, 84 and 89-96 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Brien et al.

O'Brien et al teach isolated polypeptides comprising a minimum of 30 to 50 contiguous amino acids of SEQ ID NO: 2. O'Brien et al teach isolated polypeptides comprising amino acid sequences heterologous to SEQ ID NO: 2 (See alignment attached to the enclosed reference; also see O'Brien et al: figure 1).

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***Conclusion***

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is **(703) 306-5820**. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

**JZ**

January 12, 2001



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